Remarks

Applicant's election with traverse of Group I (claims 1-15) in the reply filed on 04/27/07 has been acknowledged by the Examiner and prosecution of these claims will proceed at this time. Applicants reserve the right to file a divisional application on the withdrawn claims 16 – 20 at a later time. It must be noted however that claims 1 – 15 have been amended herein in order to place the present application in proper form for allowance and to this end some claims were amended for better grammatical structure as well as to overcome the Examiners' rejections.

Rejection under 35 USC § 112

The Examiner has rejected claims 3-10 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is asserted that the claims recite the limitation "by weight of the total mixture of the composition" and that there is insufficient antecedent basis for this limitation in the claim. The rejection is respectfully traversed for the following reasons.

Claim 1, from which claims 3 -10 depend, has now been amended herein by the insertion of the limitation "both percentages being of the total weight of the mixture of the composition". Support for this amendment can be found in claims 3 et. seq., and in the specification at page 3, lines 9 -12. Since claims 3 -10 now have proper antecedent basis, it is respectfully requested that the Examiners' rejection of the claims based on 35 U.S.C. § 112 second para., be withdrawn.

The Examiner has also rejected claim under 35 U.S.C. § 112 second para.,as being indefinite because the claim is a broader claim than claim 1, from which it depends. Claim 3, which recites the limitation of "an ester of glycerol present between about *50% and about 85%* by weight. " is asserted to be indefinite because the range of glycerol ester is outside the range claimed in claim 1, which is about 60% to about 80%. The "85%" of claim 3 falls outside of the maximum upper limit of "80%" of claim 1. This rejection is also traversed for the following reasons.

Claims 1 and 3 have now been amended whereby claim 1 now recites an ester of glycerol range of from about 50% to about 85% while claim 3, which depends there from has now been amended to recite a glycerol ester range of 60% to about 80%. Claim 3 is

now narrower than claim 1 and therefore has proper antecedent basis. The rejection of claim 3 for being indefinite under 35 U.S.C. § 112 should also be withdrawn.

II. Rejection under 35 U.S.C. § 103

Claims 1-15 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,475,510 to Venkatesh *et. al.* It is the Examiners' position that Venkatesh *et. al.*'510 teaches a fast-dispersible tablet for oral administration containing an active ingredient, a waxy material including mono-, di- or tri- aliphatic esters of glycerol,. preferably glycerol palmitostearate (Precirol®) (col. 5, lines 31-39) and a sweetener and/or a taste-masking agent to reduce bitter tasting ingredients (see col. 3, line 14 - col. 4, line 5) such as the lipoproteins and phospholipids derived from soy lecithin (col. 4, line 10 - col. 5, line 30).

The waxy material is present at a level of from about 1% to about 30%. While the Examiner admits that this range is lower than Applicant's claimed range of about 60% to about 80%, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. It is further argued that suitable or effective amounts of glycerol and/or fatty acid can be determined by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art.

Moreover, it is admitted that while Venkatesh *et al.* '510 does not explicitly teach a particle size of less than about 350 µm, it is then noted that the claim language "which can produce a particle size of less than about 350 gm" imparts future-intended use language and thus, does not afford patentable weight to the claims. Moreover, no unexpected results accrue from the instantly claimed particle size. Effective particle sizes can be determined by one of ordinary skill in the art through the routine optimization process. Therefore, Thus, given the teachings of Venkatesh *et al.* '510 delineated above, the instant invention, when taken as a whole, are asserted to be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. This rejection is also respectfully traversed for the following reasons.

The claimed compositions of the invention present comprise from about 15 to about 30% of active ingredient (principle) mixed with from about 60% to about 80% of an ester of glycerol or of a fatty acid, to which a wax is optionally added, and to which a

surfactant is added, and are prepared by a spray-cooling method which can produce a particle size of less than 350 μm. A main advantage of the compositions of the present invention is that the esters of glycerol selected and their amounts not only taste mask the bitter or irritating olefactory characteristics of many bad tasting pharmaceutical actives, but the particular glycerol esters useful in the practice of the present invention also have a suitable pH-sensitivity profile that delays dispersion and release of the active principle only on a delayed basis at acid pH conditions as encountered in the stomach. The glycerol esters then, serve to delay the release of the active until it passes the olefactory sensory system and enters the stomach. Nothing like this is disclosed in the cited prior art

The use of these glycerol esters together with the small particle size of the pharmaceutical active/glycerol ester component result in the advantage of an effective masking of taste coupled with a lack of the sandy or bitter feeling of the composition normally affiliated with said pharmaceutical active in the mouth.

The Venkatesh *et al.* '510 patent cited by the Examiner as rendering claims 1 -15 obvious under 35 U.S.C § 103 does not teach or suggest the instant claimed particle size of less than 350μ (see currently amended claim 1, and p. 2, ln. 31), nor does it teach the esters of glycerol or fatty acid as taste masking agents. The Examiner admits that the Venkatesh *et al.* '510 patent does not teach particle sizes less than 350μ and that suitable taste-masking agents in the intragranular formulation include lipoproteins and phospholipids derived from soy lecithin (col. 5, lines 40-44), not esters of glycerol. Claim 1 (and hence all the pending claims dependent therefrom has been amended herein to recite the fact that the particles of the present invention are less than 350μ. This small particle size limitation is an important inventive and functional feature of the invention since this removes the sandy or chalky feeling of the composition normally affiliated with said pharmaceutical active in the mouth.

Glycerol esters may be discussed as possible components of the intragranular formulation of Venkatesh *et al.* '510 but they are not discussed or disclosed as being useful as taste masking agents. In fact, the patent only discloses them as being waxy materials (col. 5, ln. 31 – 39) with no real function recited therein. It cannot be said that there is anything evident in the patent that teaches the combination of elements recited in the claims of the present application that are the spray-dried and cooled using a two-fluid

nozzle to ensure that the desired particle size is obtained, i.e. a particle size less than 350µ. diameter as described above. Every formulation disclosed in the Venkatesh *et al.* '510 patent is a dry granulation mixture for compaction, milling or slugging as a tablet. (see the specification and claims throughout).

The rejection of claims 1 -15 as being obvious under 35 U.S.C. § 103 should respectfully therefore, be withdrawn.

In light of the foregoing amendments to the claims and arguments as to their patentability, it is respectfully asserted that the remaining pending claims recite patentable subject matter that is clearly distinguishable and an advance over the cited prior art. It is further respectfully requested that said rejections of the claims be withdrawn so that they might pass to allowance and issue. Should however, the Examiner still have some remaining issue(s) or concern(s), he is earnestly solicited to contact the undersigned attorney so that any un-resolved matter might be overcome and resolved.

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